

## **REMARKS**

### **The Amendments**

Claim 4 is amended to remove the “neuornorm” term and thus address the 35 U.S.C. §112, second paragraph, rejection. It is submitted that the above amendment would put the application in condition for allowance or materially reduce or simplify the issues for appeal. The amendment does not raise new issues or present new matter and does not present additional claims. The amendment has been made to render moot the 35 U.S.C. §112, second paragraph, rejection made in the Final action. Thus, it was not earlier presented. Accordingly, it is submitted that the requested amendment should be entered.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

### **The Rejection under 35 U.S.C. §112, second paragraph**

The rejection of claim 4 under 35 U.S.C. §112, second paragraph, is believed to be rendered moot by the amendment to claim 4.

### **The Rejection under 35 U.S.C. §103**

The rejection of claims 1-8, 35 and 37 under 35 U.S.C. §103, as being obvious over Meissner (U.S. Patent No. 6,706,726) in view of Podolsky (US Pub. No. 2003/185838), is respectfully traversed.

Meissner discloses compounds of its formula I as anticholinergics, particularly for treating asthma or COPD (chronic obstructive pulmonary disease). Meissner does not

provide any suggestion of a composition of such compounds together with an NK<sub>1</sub> receptor antagonist.

Podolsky teaches that specific trefoil peptide compounds may be used to treat lesions of the respiratory epithelium. Use of certain trefoil peptide compounds is the main characterizing feature of Podolsky. Podolsky discloses that the lesions being treated can result from a wide variety of causes (see, e.g., page 1, paras. 0004 and 0010). It further discloses that these specific trefoil peptides may be used in combination with second therapeutic agents. Podolsky discloses a large variety of general second therapeutic agents which could possibly be used, i.e., anti-inflammatory agents, non-steroidal anti-inflammatory agents, antimicrobial agents, antihistamines, cholinergic receptor antagonists, neurokinin receptor antagonists, leukotriene receptor antagonists, decongestants, phosphodiesterase inhibitors and beta-adrenergic antagonists (see, e.g., page 1, para. 0012).

Applicants respectfully submit that one of ordinary skill in the art would not have been motivated by the reference teachings or have any other reason to combine one of the second therapeutic agents of Podolsky into the Meissner compositions or methods. Meissner is directed to methods and medicaments for treating COPD, whereas Podolsky is directed to methods and medicaments for treating lesions of the respiratory epithelium. Such lesions are not necessarily connected with COPD but are a symptom which can arise as a consequence of many of a variety of circumstances or diseases, for instance, from such varied sources as surgical intervention or intubation or by inhaling smoke, etc. (see, e.g., page 3, para. 0032, of Podolsky). One of ordinary skill in the art is not taught by Podolsky that any of its trefoil peptides or second therapeutic agents are effective to treat COPD but merely a symptom which might arise from it or from any of a number of other varied sources. COPD is only in certain situations connected with lesions of the respiratory epithelium, i.e., lesions of the

epithelium are not a general symptom in COPD. Further, lesions of the respiratory epithelium can also be caused by many different diseases and circumstances other than COPD.

For the above reasons, applicants respectfully urge that the instant facts are not in line with the citation in the Office action to In re Kerkhoven. Podolsky does not suggest the use of their second therapeutic agents to treat COPD. Thus, there is no motivation or other reason to combine any one of the second therapeutic agents of Podolsky, e.g., an NK receptor antagonist, with the anticholinergics of Meissner to treat COPD. In Kerkhoven, there was a reason to combine the two components because both were taught for the same specific use. Such is not the case here.

Further applicants urge that the In re Burckel decision cited in the Office action (and also KSR International Co. v. Teleflex Inc., 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007)) are not applicable to the instant facts. Applicants recognize that the reason for combining reference teachings need not be expressly stated in the cited references. Applicants' argument is that no reason – whether explicit, implicit or from application of common sense (see KSR) – for making the combination alleged in the Office action finds sufficient support on record. The apparent reason for combining the reference teachings is that both teach compounds for treating COPD. As discussed above, however, this reason is not supported by the facts. Podolsky does not teach that either its trefoil peptides or second therapeutic agents are should be used to treat COPD.

Even if one considered that Podolsky teaches treatment of COPD directly – which it clearly does not – one would not additionally conclude that the second therapeutic agents it teaches, e.g., NK receptor antagonists, would also be effective for treating COPD without the trefoil peptides. Podolsky just teaches that the specific trefoil peptides are effective to treat the lesions of the respiratory epithelium. Podolsky does not state whether its second

therapeutic agents are also useful for treating these lesions or have some other effect. One of ordinary skill in the art could not have a reasonable expectation that the second therapeutic agents, particularly a specific one, would be effective without being combined with the trefoil peptide.

Even if, contrary to all of the above reasons, one of ordinary skill in the art did have a reason to combine a second therapeutic agent of Podolsky into the Meissner compositions/methods, the claimed invention would still not be suggested. Podolsky teaches “neurokinin receptor antagonists” as only one broad category among a wide variety of possible second therapeutic agents. Given the broad teaching, one of ordinary skill in the art would not have been fairly directed to select this specific category of agent to combine with Meissner, particularly in view of the other distinctions discussed above. Further, Podolsky’s teaching of “neurokinin receptor antagonists” does not point one of ordinary skill in the art to the specifically claimed invention, even if this category was selected. Podolsky does not teach, specifically, NK<sub>1</sub> antagonists (i.e., neurokinin receptor type 1 antagonists). There are at least three known neurokinin receptors types and nothing in the art points one of ordinary skill in the art to specifically select the NK<sub>1</sub> antagonists.

Further, both Meissner and Podolsky are silent as to the combined effect of an anticholinergic and NK<sub>1</sub> receptor antagonist. There is no suggestion that these compounds would be compatible or that their combination would be reasonably expected to succeed for treating a respiratory disease, particularly COPD, or for any other reason.

For all of the above reasons, it is urged that the combined teachings of the prior art fail to render the claimed invention obvious to one of ordinary skill in the art and the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the application is in condition for allowance. But the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

No fee, other than the One-Month Extension of Time being paid herewith, is believed to be due with this Reply. However, the Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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